



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

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OFFICE OF
RESEARCH AND DEVELOPMENT**MEMORANDUM**

From: Robert Kavlock, Deputy Assistant Administrator for Science, Office of Research and Development, Environmental Protection Agency

To: Alfredo Gomez, Director, National Resources and Environment, Government Accountability Office

Subject: Status of the IRIS Program's Implementation of Outstanding GAO Recommendations and the GAO High Risk List

The U.S. Environmental Protection Agency (EPA) takes seriously the recommendations provided by the GAO regarding EPA's processes for assessing toxic chemicals. We are committed to taking actions that will strengthen the Integrated Risk Information System (IRIS) Program. The purpose of this memo and the accompanying corrective action plan is to document the actions taken to date, our plans for additional actions, and why we believe that sufficient progress has been made to warrant removal of GAO's high risk designation. We are confident that the actions documented in the plan will enable the IRIS Program to produce timely, transparent, and credible assessments in support of EPA's mission to protect public health and the environment. These efforts are also complimented by actions taken by the IRIS Program to address recommendations from the National Academy of Sciences (NAS) in their 2011 report, *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde*, and the 2014 report, *Review of EPA's Integrated Risk Information System (IRIS) Process*.

GAO High Risk Criteria. In 2015, the GAO High Risk Report¹ provided five new, overarching criteria to help programs gauge their progress in resolving the high risk designation. Specific to the IRIS Program, GAO found that EPA had met the criterion for Leadership Commitment, partially met criteria for implementation of an Action Plan and Monitoring, and had not met criteria for Capacity and Demonstrated Progress. Below we provide updated information on activities in the IRIS Program to address these high risk criteria.

Leadership Commitment. In the GAO 2015 High Risk report, EPA met the criteria for leadership commitment. EPA's top leadership continues to demonstrate support for improving the IRIS Program. Strong management direction and support for approaches designed to increase the IRIS Program's productivity and transparency endures. These efforts were noted by the NAS in 2014, who observed "...that there is an institutional commitment to completing the revisions of the [IRIS assessment

¹ GAO Report to Congressional Committees High-Risk Series: An Update (2015) available at <http://www.gao.gov/assets/670/668415.pdf>

development] process, even as the program continues through the current transition phase and is closely watched by both stakeholders and Congress.” The IRIS Program has sustained organizational changes and initiatives, and is including a newer focus on long-term goals and planning. As changes are implemented, senior officials in EPA provide oversight. EPA continues to demonstrate strong leadership commitment from all levels of the Agency to transform the IRIS Program to address challenges and ensure that the Agency, state and local governments, and the American public have the most rigorous, science-based information about the health effects of chemicals in the environment.

Action Plan. In 2015, GAO reported that the Agency had partially met the criterion of having an action plan for addressing recommendations. Over the last four years the IRIS Program has implemented a number of changes in response to GAO recommendations and the corrective action plan at the end of this memo addresses these recommendations. For example, building on previous efforts to estimate timelines, the IRIS Program is currently evaluating timelines and resource estimates and we will provide this information to GAO by December 2016. The corrective action plan itself is a living document, which will be continually monitored and updated as appropriate. This action plan is complemented by progress reports that have been released from 2011-2015, which document programmatic activities to address NAS recommendations²

Monitoring. According to the 2015 GAO report, the Agency had partially met the criterion of monitoring. EPA has instituted a number of monitoring activities for the IRIS Program. We successfully obtained independent validation from authoritative scientific bodies with respect to the substantial corrective measures undertaken. EPA received commendation from the NAS for the significant transformations made to the program in a short period of time and noted a successful future if the Agency continued on its trajectory. We have benefitted from consistent monitoring and independent review by EPA’s Science Advisory Board (SAB) regarding the effectiveness and sustainability of EPA’s IRIS assessment development process—including the changes made in response to the NAS’ recommendations. We have increased the availability and accuracy of current information for IRIS users with an overhaul of the IRIS website. Interactions with the NAS, the SAB, and the public provide numerous opportunities for feedback, help ensure high scientific quality, and facilitate continual evolution and improvement in the program. Additionally, the Agency increased monitoring and oversight of the IRIS Program by way of regular meetings to assess status and performance and to inform senior officials on progress and potential risks. Notably, the IRIS Program provides monthly updates to the Administrator’s office. EPA is committed to monitoring the performance of the IRIS Program and continually improving on its ability to meet the statutory, regulatory, and programmatic needs of IRIS users.

Capacity. GAO reported that the Agency had not met the criterion of capacity. EPA is dedicated to improving capacity and we have taken some important steps. The IRIS Program has established disciplinary workgroups (e.g., neurotoxicity, statistics, pharmacokinetics) and committees (e.g., science and management councils) to increase productivity and capacity by using these workgroups and committees to ensure that controversial scientific issues are presented in a balanced manner, the rationale for decisions are adequately explained, and peer review comments are appropriately

² IRIS Progress Reports and Reports to Congress are publicly available at: <https://www.epa.gov/iris/iris-progress-reports>

addressed. The roles of the various workgroups and committees, the general practices of the program, and the application of systematic review methods in IRIS assessments are being described in an IRIS Handbook of Operating Procedures that is currently under development. The Handbook is focused on specific responsibilities in the development and review of IRIS assessments and will provide direction to current staff and will speed the integration of planned new hires; these actions are anticipated to increase program capacity. The completion of the 2015 IRIS Multi-year Agenda was a major undertaking resulting in an improved understanding of the needs of EPA and focused on the priorities of the Agency. The IRIS Program evaluated the capacity needed for fully implementing the multi-year Agenda and conducted an internal workload analysis to evaluate the program's need for people, skills, and resources. As a result of this analysis, we have implemented an aggressive recruitment plan for hiring 20 additional scientists from an array of disciplines and at different skill levels. We have maximized our resources to address user needs by working with EPA program and regional offices to coordinate planning and activities when there are data gaps and when it may be appropriate to use alternative sources of toxicity information. The IRIS Program continues to prioritize needs and to identify and evaluate the demand for IRIS toxicity assessments needed to meet and maintain users' needs.

Demonstrated Progress. In 2015, GAO also reported that the Agency had not met the criterion of showing demonstrated progress. We believe that progress should not be measured only by the posting of a final IRIS assessment. Progress should also measure the corrective actions that have been implemented and sustained in concert with extensive efforts to increase scientific quality, improve transparency, and incorporate enhancements to the assessment process in response to the 2011 and 2014 NAS recommendations. The IRIS Program is demonstrating progress by producing numerous interim products that are foundational to the assessments (i.e., preliminary materials, public and peer review drafts of assessments) as well as conducting overarching activities aimed at improving assessment quality and efficiency (e.g., developing systematic review methods and an IRIS handbook of operating procedures). It is important to advance chemicals at every stage of the IRIS process, and the movement of multiple assessments through the rigorous IRIS process is progress. We have extensively restructured assessments already under development by incorporating systematic review methods. We have submitted three assessments for public comment so far this year and will release two final IRIS assessments in September and two more by January, 2017. Over the last 4 years, we have held numerous workshops and public science meetings to discuss and resolve key science issues that supported the development of high quality assessments. Together, these efforts have yielded results as evidenced by the very favorable peer review comments received on recent draft assessments. As the IRIS Program is implementing these actions to improve the transparency, clarity, and scientific rigor of our assessments, we also reiterate our commitment to continue to increase productivity as measured by an increased number of interim products as well as final assessments to meet the needs of the Agency and the public. IRIS is the recognized world-wide "gold standard" for toxicological assessments and the improvements implemented as a result of the GAO and NAS recommendations should be considered as EPA having achieved demonstrated progress.

Conclusion. Recommendations from the GAO, NAS, and others have led to fundamental changes in the activities of the IRIS Program. The program has embraced these recommendations and is committed to addressing them, as well as periodically re-evaluating the effectiveness of implementation. The IRIS Program is focused on continual improvement, implementation of GAO recommendations, and moving beyond those recommendations to address future challenges in the evaluation of the health hazards of

chemicals found in the environment. The actions implemented by the IRIS Program, the progress made, and the program's continued commitment to excellence have made a difference and have been noticed by the NAS, SAB, as well as stakeholders and the public. At their core, these changes have improved the quality, transparency, and efficiency of the IRIS Program. Further, EPA has extensive commitment from leadership across the Agency to improve the IRIS Program, including increasing the capacity within the program and implementing the action plan. We believe that the IRIS Program has demonstrated significant progress in addressing GAO's recommendations to warrant a reconsideration of the high-risk designation.

Corrective Action Plan for the IRIS Program

GAO Recommendation and EPA Response	Specific EPA Corrective Actions	Status
GAO-08-40 Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System (April 2008)		
<p><u>GAO:</u> <i>In addition, the EPA Administrator should take steps to better ensure that EPA has the ability to develop transparent, credible IRIS chemical assessments—an ability that relies in large part on EPA's independence in conducting these important assessments. Actions that are key to this ability include ensuring that EPA can determine the types of IRIS assessments to conduct on the basis of the needs of EPA's program offices and other users.</i></p> <p><i>In June 2011, we requested information from EPA on planned or completed actions responsive to this recommendation.</i></p> <p>GAO will need an update from EPA on this recommendation. We will need an update on the Interagency Review Process that addresses the following questions: (1) What agencies participate in meetings and regularly provide comments on draft IRIS assessments? (2) Are all interagency comments being made available to the public via the IRIS web page? (3) Does EPA make the independent decision to move assessments to external peer review or issuance? In addition, we need confirmation regarding whether the December 2015 IRIS Agenda considered the needs of EPA's program offices. Did the Agenda take into consideration other user's needs – why or why not?</p>	<p>EPA developed and released the IRIS multi-year agenda based on a prioritization of assessment needs formally solicited from EPA's program and regional offices, the IRIS Program's primary clients.</p> <p>EPA developed a formal scoping process for each IRIS assessment that solicits input from EPA program and regional offices in order to identify the scope of an assessment prior to its initiation, consistent with recommendations in the NAS (2009) <i>Science and Decisions</i> report.</p> <p>EPA released scoping information for the following IRIS chemicals: arsenic, diethyl phthalate, hexabromocyclododecane, ethylbenzene, naphthalene, diisomonyl phthalate, butyl benzyl phthalate, diisobutyl phthalate, dibutyl phthalate, and polychlorinated biphenyls.</p> <p>EPA developed a formal problem formulation process for each IRIS assessment that solicits input on science issues to be addressed in the assessment from EPA program and regional offices and other users (including stakeholders and the general public).</p> <p>EPA has implemented a number of corrective actions in response to this GAO recommendation, and addressed the specific questions above in other communications with GAO. Central to this response was the establishment of a multi-year agenda, developed in coordination with program and regional offices, and benefited from increased awareness of the priorities and timing of agency needs for specific IRIS assessments. Increased communication and awareness of Agency needs has also been integrated into the assessment development process itself, with the establishment of an internal scoping process to ensure that assessments meet Agency needs (e.g., identifying forms of a chemical, routes of</p>	<p>IMPLEMENTED – Dec. 2015</p> <p>IMPLEMENTED – Sept. 2012</p> <p>COMPLETED</p> <p>IMPLEMENTED – July 2014</p> <p>COMPLETED</p>
		<p>ONGOING and PLANNED</p>

GAO Recommendation and EPA Response	Specific EPA Corrective Actions	Status
<p>exposure, etc.). EPA is committed to sustaining this activity in the IRIS Program, in future releases of multi-year agendas, with formalized scoping with Agency partners (as well as problem formulation), and continual, regular communications within the Agency to maintain a dialogue on IRIS Program activities.</p>	<p>EPA organized and convenes monthly meetings with program and regional office partners to ensure continuing dialogue on their needs related to IRIS assessments.</p>	IMPLEMENTED – May 2014
<p><i><u>GAO: To develop timely chemical risk information that EPA needs to effectively conduct its mission, the Administrator should require the Office of Research and Development to re-evaluate its draft proposed changes to the IRIS assessment process in light of the issues raised in this report and ensure that any revised process establishes a policy that endorses conducting IRIS assessments on the basis of peer-reviewed scientific studies available at the time of the assessment and develops criteria for allowing assessments to be suspended to await the completion of scientific studies only under exceptional circumstances.</u></i></p>	<p>EPA revised the IRIS Process to bring management of the process under EPA's purview, which streamlined the review schedule, maintained scientific integrity, and increased transparency (e.g., began making comments received from other federal agencies publicly available).</p>	IMPLEMENTED – May 2009
<p><i>In June 2011, we requested information from EPA on planned or completed actions responsive to this recommendation.</i></p> <p><i>GAO will need an update from EPA on this recommendation, with responses to the following questions: (1) Has EPA used the July 2013 "Stopping Rules" on any assessments? If so, please tell us which assessment they were used on and the justification for suspending the assessment. If they have not been used, please explain why.</i></p>	<p>EPA established "Stopping Rules" to allow assessments to be conducted based on the peer reviewed scientific studies available at the time of assessment and to describe the conditions under which new information or studies should be included in an assessment to minimize suspension/delay while awaiting completion of scientific studies.</p> <p>EPA enhanced the IRIS Process to improve the scientific integrity of assessments, improve the productivity of the Program, and increase transparency so issues are identified and debated early in assessment development.</p>	IMPLEMENTED – July 2013

EPA: By publicly posting the "stopping rules" in July 2013, EPA has directly addressed the GAO recommendation to establish a policy that balances the need to conduct assessments in a timely manner with making sure that final assessments are based on the most recent peer-reviewed scientific literature. Additionally EPA has instituted changes in the development of IRIS assessments that facilitate identifying new research earlier in draft development. The development of literature search protocols, and subsequently sharing and seeking comment on the protocols and results with the public early in draft development ensures that EPA is aware of all relevant studies.

GAO Recommendation and EPA Response	Specific EPA Corrective Actions	Status
<p><u>GAO:</u> To develop timely chemical risk information that EPA needs to effectively conduct its mission, the Administrator should require the Office of Research and Development to re-evaluate its draft proposed changes to the IRIS assessment process in light of the issues raised in this report and ensure that any revised process periodically assesses the level of resources that should be dedicated to this significant program to meet user needs and maintain a viable IRIS database.</p> <p>In June 2011, we requested information from EPA on planned or completed actions responsive to this recommendation.</p> <p>GAO will need an update from EPA on this recommendation, with responses to the following questions: (1) Did the December 2015 IRIS Agenda take into consideration the level of resource that should be dedicated to the program and each assessment? If so, please provide a description and documentation of this consideration. If not, please let us know why resources were not taken into consideration when developing the 2015 IRIS Agenda.</p>	<p>EPA estimated the level of effort needed to complete each IRIS assessment that is part of the multi-year agenda, as well as the staff expertise required for the IRIS Program in order to meet user needs.</p> <p>EPA assessed the staffing needs within the IRIS Program, and established a hiring plan to bring in approximately 20 new scientists from a range of disciplines over the next year.</p> <p>EPA created an IRIS Management Council that meets weekly to ensure efficient operation of the IRIS Program by making program-wide decisions about priorities and resource commitments.</p> <p>EPA conducts annual budget and operations planning to ensure appropriate resources are available to develop IRIS assessments.</p>	<p>IMPLEMENTED – Nov. 2014</p> <p>IMPLEMENTED – May 2015 and ONGOING</p> <p>IMPLEMENTED – MAY 2013</p> <p>ONGOING</p>
<p><u>EPA:</u> EPA is committed to making sure that decisions on IRIS Program activities incorporate consideration of resource levels, both in terms of financial resources as well as staffing. Specifically, this was exemplified in the development of the multi-year agenda, which incorporated feedback from program and regional offices to prioritize assessments for future development, as well as an internal evaluation of IRIS Program resources and expertise that would be needed to start new assessments. The establishment of a management council, ongoing budget and operations planning, new hiring, as well as recent program and project management activities in the IRIS Program are further evidence that EPA has made significant progress in evaluating and making sure that resources are appropriate to meet IRIS Program user needs.</p> <p>GAO-12-42 Chemical Assessments: Challenges Remain with EPA's Integrated Risk Information System Program (January 2012)</p> <p><u>GAO:</u> To better ensure the credibility of IRIS assessments by enhancing their clarity and transparency, the EPA Administrator should require the Office of Research and Development to submit for independent review to an independent entity with scientific and technical credibility, such as EPA's</p>	<p>EPA contracted with NAS to conduct a review of the IRIS assessment development process, and changes planned or made in response to the 2011 NAS report on formaldehyde.</p>	<p>COMPLETED – May 2014</p>

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<p><i>Board of Scientific Counselors, a plan for how EPA will implement the National Academies' suggestions for improving IRIS assessments in the "roadmap for revision" presented in the National Academies' peer review report on the draft formaldehyde assessment.</i></p> <p>EPA: EPA has demonstrated its commitment to making sure that the IRIS Program's actions in response to the 2011 NAS report recommendations benefit from further input by independent entities. This is best exemplified through EPA's actions to contract with the NAS to conduct a review of the IRIS assessment development process that was completed in 2014. This review directly addressed, and endorsed, the direction of the IRIS Program in responding to recommendations from the 2011 report. EPA has also established an independent review committee (the CAAC) as part of the Science Advisory Board, that provides input on specific assessments and will also provide feedback on the direction of the IRIS Program in future meetings. Along with the other corrective actions described here, EPA has not only completed a review by an authoritative body (the NAS) on the IRIS Program's activity, but also established a means to receive future input.</p>	<p>EPA established a dedicated Science Advisory Board Chemical Assessment Advisory Committee (SAB CAAC) to provide continuing, consistent review of IRIS assessments and comment on the implementation of NAS recommendations in specific IRIS assessments.</p> <p>EPA is planning to convene a general meeting of the full SAB CAAC to solicit feedback on the direction of the IRIS Program, and implementation of the 2011 and 2014 NAS recommendations.</p>	<p>IMPLEMENTED – Jan. 2013</p> <p>PLANNED – Winter 2017</p>
	<p>EPA convened public workshops on the NAS recommendations, including two focused on systematic review, a key NAS recommendation, which engaged the public and scientific stakeholders to provide feedback on the implementation of NAS recommendations.</p>	<p>COMPLETED – Aug. 2013, Oct. 2014, Dec. 2015</p>
	<p>EPA submitted for review by the SAB CAAC four IRIS assessments that incorporate NAS recommendations (trimethylbenzenes, ammonia, ethylene oxide, and benzo[a]pyrene).</p>	<p>COMPLETED – Aug. 2013, Aug. 2013, Aug. 2014, and Sept. 2014</p>
<p><i>GAO: To better ensure the credibility of IRIS assessments by enhancing their timeliness and certainty, the EPA Administrator should require the Office of Research and Development to assess the feasibility and appropriateness of the established time frames for each step in the IRIS assessment process and determine whether different time frames should be established, based on complexity or other criteria, for different types of IRIS assessments.</i></p>	<p>EPA established and regularly convenes scheduled IRIS Public Meetings, in which stakeholders can provide input on the implementation of the NAS recommendations in draft IRIS assessment materials.</p> <p>EPA committed that the public comment draft of the IRIS assessment for formaldehyde will address all the 2011 recommendations and many of the 2014 recommendations from the NAS. The ethylbenzene and naphthalene assessments (and subsequent assessments) will address the recommendations from both reports.</p> <p>EPA revised the IRIS Process to better establish realistic timelines for assessment development, including the distinction between two sets of timelines for the development of "standard" and "complex" IRIS assessments.</p>	<p>IMPLEMENTED – Dec. 2013</p> <p>PLANNED – Winter 2017</p> <p>(ethylbenzene and naphthalene) and Summer 2017 (formaldehyde)</p> <p>COMPLETED – July 2013</p> <p>COMPLETED – April 2009, and July 2013</p>

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<p><u>EPA:</u> As detailed in the corrective actions, EPA has periodically engaged in activities to document the timelines for assessment development. In recent years those timelines have fluctuated with implementation of recommendations from the NAS. Accordingly, EPA has already initiated re-evaluation of timelines for standard and complex assessments. Internal efforts, including a "lean"³ event in 2015 and program/project management initiatives in 2016 will inform this reevaluation, which will provide realistic, up-to-date timeframes reflective of advances in the IRIS Program's assessment development process.</p>	<p>enhanced, and has repeatedly assessed the feasibility and appropriateness of these timelines.</p> <p>EPA held a Lean event to evaluate the existing process in the context of client (program and regional offices) needs, and identify more realistic processes and timelines for assessment development after determining the 2013 timelines did not adequately account for process changes in response to NAS recommendations.</p> <p>EPA contracted with independent Project Management Professionals to identify and establish effective management practices for ongoing projects and resources, to create stability, reliability, and predictability in planning, and reevaluate timelines for assessment development.</p> <p>EPA is evaluating steps 2 through 7 of the current IRIS assessment process, and expects to establish new assessment timelines for each of these steps. (Completion planned for end of 2016).</p>	<p>COMPLETED – Aug. 2015</p> <p>ONGOING</p>
<p><u>GAO:</u> To better ensure the credibility of IRIS assessments by enhancing their timeliness and certainty, the EPA Administrator should require the Office of Research and Development, should different time frames be necessary, to establish a written policy that clearly describes the applicability of the time frames for each type of IRIS assessment and ensures that the time frames are realistic and provide greater predictability to stakeholders.</p>	<p>EPA is reevaluating established timelines consistent with ongoing program management initiatives impacting draft development and review. Revised timelines are expected to be established by the end of 2016.</p> <p>EPA will make general information on timelines available on the IRIS website (www.epa.gov/iris).</p>	<p>ONGOING</p>
	<p><u>EPA:</u> Consistent with the previous recommendation, EPA has periodically evaluated timeframes for the IRIS assessment development process, which have fluctuated as the IRIS Program implements NAS recommendations. Updated timelines are expected to be established by the end of 2016, and general information on these updated timelines will be made available on the IRIS website. These actions are consistent with other activities to provide greater predictability to stakeholders, including the release of a multi-year agenda which provides stakeholders advanced notification of</p>	<p>PLANNED by the end of 2016</p>

³ IRIS underwent a Leanovations/Kaizen event to "Lean" the IRIS draft assessment development process (Step 1 of the IRIS process). Lean is a set of principles and tools that help people learn to see and eliminate waste. Lean methods improve productivity and reduce waste within a process by engaging staff to help identify and make improvements to the process. EPA has embraced Lean and is implementing this process in a number of programs. The key benefit for the IRIS Program is the enhanced opportunity to focus work resources on higher value activities and services to the clients (i.e., EPA program and regional offices) by eliminating non-value added activities.

GAO Recommendation and EPA Response	Specific EPA Corrective Actions	Status
<p>which assessments will be initiated by the program in the near future, as well as increased communications activities to improve outreach.</p> <p>GAO: <i>To ensure that current and accurate information on chemicals that EPA plans to assess through IRIS is available to IRIS users--including stakeholders such as EPA program and regional offices, other federal agencies, and the public--the EPA Administrator should direct the Office of Research and Development to annually publish the IRIS agenda in the Federal Register each fiscal year.</i></p>	<p>EPA established and made publicly available an IRIS multi-year agenda that identifies the chemicals which are of the highest priority to the Agency for assessment. EPA plans to periodically update the multi-year agenda to reflect changes in Agency priority over time (based on input from program and regional offices).</p>	COMPLETED – Dec. 2015
<p>EPA: EPA has implemented this recommendation – to ensure current and accurate information is available to IRIS users – through a number of corrective actions described here. These actions, implemented with the intent to increase transparency, provide IRIS users, including program and regional offices, other federal agencies, stakeholders, and the public, extensive information on the chemicals currently under development in the IRIS Program, as well as those that will be started in the near future. The implementation of corrective actions led to an increased understanding of the information relevant to users, and the level of engagement needed to ensure that program and regional office needs are appropriately considered. As such, the approach to develop and utilize a multi-year agenda rather than a less detailed, annual agenda was initiated. The multi-year agenda, announced in a federal register notice and posted on the IRIS website, reflects greater input from program and regional office partners, and combined with increased communication initiatives from the IRIS Program, provides IRIS stakeholders multiple ways of staying aware of IRIS Program activities and meets the intent of this GAO recommendation.</p>	<p>EPA published a federal register notice that provided information on 1) where to find the status of specific IRIS assessments and associated materials, 2) announce the availability of a general comments docket, 3) the dates of public science meetings for the upcoming year, and 4) how to obtain information on IRIS activities by email. This notice will be posted annually.</p>	COMPLETED – Mar. 2016 and ONGOING
<p>GAO: <i>To ensure that current and accurate information on chemicals that EPA plans to assess through IRIS is available to IRIS users--including stakeholders such as EPA program and regional offices, other federal agencies, and the public--the EPA Administrator should direct the Office of Research and Development to indicate in published IRIS agendas which chemicals EPA is actively assessing and when EPA plans to start assessments of the other listed chemicals.</i></p>	<p>EPA provided updated, current, and accurate (as well as historical) information about individual chemicals that EPA is assessing in the IRIS Program (www.epa.gov/iris/list/agenda) as part of changes to EPA's website structure.</p>	IMPLEMENTED – Dec. 2015
	<p>EPA holds monthly meetings between IRIS Program management and program and regional office representatives to solicit input.</p>	IMPLEMENTED – May 2014
	<p>EPA will announce initiation of new assessments on the IRIS website, as well as through the IRIS and HHRA Listservs, reaching more than 10,000 stakeholders.</p>	PLANNED
	<p>EPA holds regular meetings with IRIS interagency reviewers.</p>	IMPLEMENTED – August 2013
	<p>EPA updated and maintains the IRIS calendar on the IRIS website, with current schedules of public events and activities including meetings, stakeholder-requested meetings, workshops, and peer review activities.</p>	COMPLETED – Dec. 2015 and ONGOING
	<p>EPA released a multi-year agenda, which lists assessments under active development and their current status, as well as a prioritized list of new IRIS assessments that EPA plans to start over the next few years.</p>	COMPLETED – Dec. 2015
	<p>EPA redesigned the IRIS website to ensure that current and accurate information on chemicals that the IRIS Program is</p>	COMPLETED – Oct. 2015

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<p>EPA: EPA has ensured that current and accurate information on chemicals in the IRIS pipeline, as well as identification of new assessments that the program will initiate, is available on the IRIS website. Critical to accomplishing this task was the release of the multi-year agenda in 2015, which identified which assessments were under active development in the IRIS Program, as well as those that the IRIS Program anticipates starting in the next few years. The transition from publishing an annual agenda to a multi-year agenda is appropriate given current timeframes for assessment development, as well as to allow for more thorough involvement of program and regional offices in identifying candidate chemicals for new assessments. The redesign of the IRIS website has also resulted in chemical-specific web pages that provide more information on assessments under development, and supporting more transparent tracking of assessments in progress.</p>	<p>EPA: To ensure that current and accurate information on chemicals that EPA plans to assess through IRIS is available to IRIS users--including stakeholders such as EPA program and regional offices, other federal agencies, and the public--the EPA Administrator should direct the Office of Research and Development to update the IRIS Substance Assessment Tracking System (IRISTRack) to display all current information on the status of assessments of chemicals on the IRIS agenda, including projected and actual start dates, and projected and actual dates for completion of steps in the IRIS process, and keep this information current.</p>	<p>EPA: EPA has made significant progress to address this recommendation and taken steps to ensure that information on chemicals is current accurate on the IRIS Website. As a result of the October 2015 IRIS website redesign, the IRISTRack database is no longer needed. The redesign of the website provides easier navigation and access to information, primarily through the use of chemical-specific web-pages. The Quick Check portion of the website provides rapid access to all assessments under active development, and the chemical specific pages contain current (and historical for completed assessments) information on timelines, including anticipated or actual dates for release of assessment materials. As the IRIS Program gains more confidence in sharing accurate date projections, taking into account ongoing programmatic changes in response to NAS and GAO recommendations, it will provide that information on the IRIS website.</p>
	<p>EPA overhauled and redesigned the IRIS website to provide stakeholders easy access to current and accurate information regarding the status and schedules of ongoing assessments (replacing the IRISTRack database).</p>	<p>COMPLETED – Oct. 2015</p>
	<p>EPA provided a table of the ongoing chemical assessments categorized by the step in the IRIS process (the IRIS QuickCheck), as well as chemical specific web pages with detailed information including status, schedule information with anticipated or actual dates, assessment history, links to draft materials, and other assessment related information.</p>	<p>COMPLETED – Oct. 2015 and ONGOING</p>
	<p>EPA maintains and enhances the IRIS website on a continual bases to keep information current.</p>	<p>ONGOING</p>
	<p>EPA will incorporate updated timeframes into posted schedules for new individual IRIS assessments.</p>	<p>PLANNED</p>

GAO Recommendation and EPA Response	Specific EPA Corrective Actions	Status
GAO-13-369 Chemical Assessments: An Agencywide Strategy May Help EPA Address Unmet Needs for Integrated Risk Information System Assessments (June 2013)		
<p><u>GAO:</u> To ensure that EPA can measure the IRIS program's performance and determine the number of IRIS toxicity assessments required to meet the statutory, regulatory, and programmatic needs of IRIS users, the EPA Administrator should direct the Office of Research and Development to document how EPA applies its IRIS toxicity assessment selection criteria, including the circumstances under which program offices and regions may or may not need an IRIS toxicity assessment.</p>	<p>EPA: Since 1998, EPA has documented the selection criteria for which chemicals are selected for IRIS assessments. Those criteria were publicly described in Federal Register notices accompanying the call for nominations of chemicals to the IRIS agenda, and were also used in the development of the 2015 multi-year agenda. Inherent in the nomination process is input and relative prioritization that reflects whether program and regional offices need or do not need an IRIS chemical assessment. The application of selection criteria was most recently executed in the development of the 2015 multi-year agenda. The compilation and analysis of information relevant to the selection criteria, combined with both the estimation of the levels of effort needed and further prioritization from program and regional offices, resulted in the identification of 15 priority chemicals for the multi-year agenda. These efforts, facilitated by the application of selection criteria and strong communication with the program and regional offices, will be maintained and implemented in the development of future agendas.</p> <p><u>GAO:</u> To ensure that EPA maximizes its limited resources and addresses the statutory, regulatory, and programmatic needs of EPA program offices and regions when IRIS toxicity assessments are not available, and once demand for the IRIS Program is determined, the EPA Administrator should direct the Deputy Administrator, in coordination with EPA's Science Advisor, to develop an agencywide strategy to address the unmet needs of EPA program offices and regions that includes, at a minimum: (1) coordination across EPA offices and with other federal research agencies to help identify and fill data gaps that preclude the agency from conducting IRIS toxicity assessments, and (2) guidance that describes alternative sources of toxicity information and when it would be appropriate to use them when IRIS values are not available, applicable, or current.</p>	<p>EPA requested chemical-specific information and prioritization rankings from program and regional offices.</p> <p>EPA incorporated information from program and regional offices, during the development of the multi-year agenda, in internal working tables and charts. This input informed whether a specific program office did or did not need an IRIS assessment for a given chemical.</p> <p>EPA conducted preliminary scoping and problem formulation to compile information and estimate resources for top priority chemicals.</p> <p>EPA worked across the agency to develop a consensus list of chemicals for assessment by IRIS.</p> <p>EPA describes, in Federal Register notices, the opportunity to nominate chemicals for an IRIS assessment, as well as its six general criteria to inform the selection of chemicals for assessment or reassessment by the IRIS Program.</p> <p>EPA documented the application of its IRIS assessment selection criteria in the development of IRIS agendas by recording information specific to these criteria in internal working tables and charts, and ranked chemicals for selection based on the criteria and program and regional office input.</p> <p>EPA maintains awareness of current program and regional office needs and priorities through monthly meetings.</p> <p>EPA held a series of meetings with the program and regional offices and IRIS management to identify EPA's unmet needs and develop a plan to address those needs, culminating in the multi-year agenda.</p> <p>EPA established a series of internal IRIS outreach and communications activities including monthly meetings with representatives of all program and regional offices and routine meetings with managers from individual offices.</p> <p>EPA established a workgroup with the National Toxicology Program to facilitate greater communication and strengthen interactions and collaboration between organizations, and undertake joint efforts towards</p>

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<u>EPA:</u> EPA has significantly increased the IRIS Program's engagement with a variety of entities including EPA program and regional offices, other federal agencies, stakeholders, and the public. EPA has met the intent of this recommendation by improving and maintaining routine communication, collaboration, and coordination across the agency with respect to IRIS values or situations in which IRIS values are not available, applicable, or current. Additionally, EPA has addressed this recommendation by increasing coordination with other federal research agencies on assessments and incorporating into the IRIS process significant opportunities for early engagement with other agencies, stakeholders, and the public to identify data gaps and discuss issues with toxicity information.	identifying and filling data gaps for chemicals of public health interest. EPA co-chairs the Toxics and Risk Subcommittee of the National Science and Technology council to create a sustainable network for the purpose of cross-government communication, coordination, and collaboration on the general risk assessment process in the federal sector. EPA coordinates with other agencies on specific IRIS assessments (e.g., arsenic, ethylene oxide), routinely seeks input from experts from other federal agencies at IRIS public science meetings. EPA implemented a problem formulation step early in the assessment development process to help identify data gaps that may impact timely completion of a chemical assessment.	ONGOING ONGOING IMPLEMENTED – July 2014 ONGOING
<u>GAO:</u> To ensure that the Environmental Protection Agency (EPA) can measure the Integrated Risk Information System (IRIS) program's performance and determine the number of IRIS toxicity assessments required to meet the statutory, regulatory, and programmatic needs of IRIS users, the EPA Administrator should direct the Office of Research and Development to identify and evaluate demand for the IRIS Program to determine the number of IRIS toxicity assessments and resources required to meet users' needs.	EPA held a series of meetings with the program and regional offices and IRIS management to identify EPA's unmet needs and develop a plan to address those needs, culminating in the multi-year agenda. EPA implemented a hiring plan for the IRIS Program in order to fully implement the multi-year agenda, and is in the process of hiring approximately 20 new scientists from a range of disciplines.	COMPLETED – 2014-2015 and Dec. 2015 (multi-year agenda) ONGOING
<u>EPA:</u> EPA has made significant progress in addressing this recommendation by embarking on a comprehensive, cross-agency process for developing the first ever IRIS multi-year agenda. By working across the Agency, EPA's IRIS Program was able to determine the high priority IRIS toxicity assessments that are required to meet the needs of IRIS users over the next few years. While finalizing the multi-year agenda, the Agency	EPA established a series of internal IRIS outreach and communications activities including monthly meetings with representatives of all program and regional offices and routine meetings with managers from individual offices.	COMPLETED – May 2014 and ONGOING

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considered resources and expertise needed to conduct priority chemical assessments, and initiated an aggressive hiring plan to increase resources in the IRIS Program to meet Agency needs.		